



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0052]

Documenting Electronic Data Files and Statistical Analysis Programs; Draft Guidance for Industry; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice of availability that published in the *Federal Register* on May 21, 2018. In that document, FDA requested comments on the draft revised guidance for industry (GFI) #197 entitled “Documenting Electronic Data Files and Statistical Analysis Programs.” The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published May 21, 2018 (83 FR 23468). Submit either electronic or written comments on the draft revised guidance by October 18, 2018, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0052 for "Documenting Electronic Data Files and Statistical Analysis Programs." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Virginia Recta, Center for Veterinary Medicine (HFV-160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0840, virginia.recta@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In the *Federal Register* of May 21, 2018, FDA published a notice announcing the availability of draft revised GFI #197 entitled “Documenting Electronic Data Files and Statistical Analysis Programs” with a 60-day comment period. We requested comments about informing sponsors of recommendations for documenting electronic data files and statistical analyses submitted to CVM to support new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review data submissions and to simplify submission preparation by providing a recommended documentation framework.

The Agency has received a request for a 90-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a comprehensive response.

FDA has considered the request and is extending the comment period for the notice of availability for 90 days, until October 18, 2018. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments.

Dated: July 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.